

**999 COLD REMEDY GRANULAR- acetaminophen, chlorpheniramine maleate granule**  
**China Resources Sanjiu Medical & Pharmaceutical Co Ltd**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**999 COLD REMEDY GRANULAR**

**Active Ingredients**

Acetaminophen	200 mg
Chlorpheniramine Maleate	4 mg

**Purpose**

Acetaminophen	Pain Reliever/Fever Reducer
Chlorpheniramine Maleate	Antihistamine

**Uses**

Temporarily relieves the following symptoms associated with the common cold, hay fever, or other upper respiratory allergies:

- minor aches and pains
- headache
- sneezing
- muscular aches
- itchy, watery eyes
- sore throat
- running nose
- fever
- itching of the nose or throat

**Warnings**

- Do not use if
- pain lasts more than 10 days
- fever lasts more than 3 days

**Ask a doctor before using if you have**

- Glaucoma
- A breathing problem such as emphysema or chronic bronchitis
- Difficulty in urination due to enlargement of the prostate gland
- Taking sedatives or tranquilizers

**As a doctor or pharmacist before you use if you are**

Taking sedatives or tranquilizers

**When using this product**

may cause excitability, especially in children

may cause drowsiness, if used with alcohol, sedatives or tranquilizers

use caution when driving a motor vehicle or operating machinery

**Stop use and consult a doctor**

if pain or fever persists or worsen

if redness or swelling is present

if symptoms last for more than 7 days

if new symptoms occur such as rash, nausea or vomiting

**Warnings**

If pregnant or breastfeeding, ask a health professional before using.

**Stop use and consult a doctor**

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

**Directions**

Adults and children 12 years of age and older: take a capsules each time, three times a day.

Children under 8 years of age: consult a doctor before using.

**Other information**

Protect from light and excessive heat

Keep tightly closed

Keep in a dry place

**Other Ingredients**

Caffeine

Melicope Pteleifolia Leaf

Bidens Pilosa

Dendranthema Indicum Flower

Ilex Pedunculosa Whole

**Drug Facts**

文件名	CP2011-10-0432 感冒靈颗粒(美国注册特刊).ai	制作者	陈敏	传票	CP2011-10-0432	条码等级	
颜色	C M K 专绿	日期	2011-10-17	文件路径	\\server\cp\制作区\NS\2011年9月\CP2011-09-0542\out		
尺寸	85*75*75 mm						



**Drug Facts 藥品資訊**

Active ingredients 有效成分	Purpose 用途
Acetaminophen 對乙酰氨基酚 200mg	Pain reliever/Fever reducer 解熱止痛
Chlorpheniramine Maleate 氯苯那敏 maleate 4mg	Antihistamine 抗組織胺

**Other Ingredients 輔助成份**  
 Caffeine 咖啡因, Melissa Pelefolia Leaf 三葉草, Biskaya Pilosa Whole 金雞納樹, Desmodium Indicanum Flower 野靛藍, Rauwolfia Serpentina Whole 葉柳

**Uses 作用**  
 Temporarily relieves the following symptoms associated with the common cold, hay fever, or other upper respiratory irritation: 暫時緩解傷風、花粉症或對其他上呼吸道引起下列症狀:  
 ■ Minor aches and pains 輕度痠痛 ■ Headache 頭痛 ■ Cough 咳嗽  
 ■ Muscular aches 肌肉酸痛 ■ Itchy, watery eyes 發癢、流淚  
 ■ Runny nose 流鼻涕 ■ Sneezing 打噴嚏  
 ■ Itching of the nose or throat 鼻或喉發癢 ■ Fever 發熱

**Warnings 警誡**  
 Do not use if you have the following conditions:  
 ■ Pain lasts more than 10 days 疼痛十天以上  
 ■ Fever lasts more than 5 days 發燒五天以上  
 ■ If pregnant or breast-feeding, ask a health professional before using. 如懷孕或哺乳中, 在服用本品前請先諮詢醫師。  
 Ask a doctor before using if you have any of the following conditions. 在服用本品前請先諮詢醫師。  
 ■ Stomach problems 胃部問題  
 ■ A breathing problem such as emphysema or chronic bronchitis 呼吸系統問題如氣管炎或慢性支氣管炎  
 ■ Difficulty in urination due to enlargement of the prostate gland 前列腺肥大引起排尿困難



**Drug Facts 藥品資訊 (continued) 續**

Ask a doctor or pharmacist before you use if you are:  
 ■ Taking medicines or supplements 正在服用藥物或補充劑  
 ■ Taking sedatives or tranquilizers 正在服用安眠藥

**When using this product 在服用本品時**  
 ■ May cause drowsiness, especially in children 可能會引起疲倦、嗜睡、困倦。  
 ■ May cause drowsiness, if used with alcohol, sedatives, or tranquilizers. 可能會引起疲倦、嗜睡、困倦。勿與酒精或安眠藥同時服用。  
 ■ Use caution when driving a motor vehicle or operating machinery. 駕駛車輛或操作機械時請小心。  
 ■ Stop use and consult a doctor if you have the following conditions: 請停止服用並請諮詢醫師。  
 ■ If pain or fever persists or worsens or lasts longer than 7 days 疼痛或發燒持續七天以上。  
 ■ If redness or swelling is present 紅腫  
 ■ If symptoms last for more than 7 days 症狀持續七天以上  
 ■ If new symptoms occur such as rash, nausea or vomiting. 出現新的症狀如紅疹、嘔吐、噁心或嘔吐。  
 Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms. 請遠離兒童。如不慎服用過多, 請立即尋求醫療協助或聯絡中毒控制中心 (Poison Control Center) 聯絡。即使你沒有察覺任何中毒症狀, 這仍可能導致嚴重甚至危及生命的中毒反應。

**Directions 用法**  
 ■ Adults and children 12 years of age and older: Take 1 bag each time, three times a day, after meals and before bedtime. 成人及12歲以上兒童: 每次一包, 每日三次, 飯後及睡前服用。  
 ■ Children under 6 years of age: Consult a doctor before using. 年齡在6歲以下的兒童: 切勿服用, 諮詢醫師。

**Other Information 其他注意事項**  
 ■ Protect from light and excessive heat 避光及避熱  
 ■ Keep tightly closed 緊閉蓋子  
 ■ Keep in dry place 放在乾燥處

Made in China



<b>999 COLD REMEDY GRANULAR</b>			
acetaminophen, chlorpheniramine maleate granule			
<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12753-307
Route of Administration	ORAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	Acetaminophen (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	Acetaminophen	200 mg in 90 g
	Chlorpheniramine Maleate (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	Chlorpheniramine Maleate	4 mg in 90 g
<b>Inactive Ingredients</b>			
	<b>Ingredient Name</b>		<b>Strength</b>

<b>Caffeine</b> (UNII: 3G6A5W338E)	
<b>MELICOPE PTELEIFOLIA LEAF</b> (UNII: 1I20C6Y98D)	
<b>Bidens Pilosa Whole</b> (UNII: AYT02NS64S)	
<b>Dendranthema indicum flower</b> (UNII: I6OER6U04L)	
<b>ilex Pedunculosa whole</b> (UNII: 46804GL8SN)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	2 pieces
<b>Shape</b>	SQUARE	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12753-307-02	10 g in 1 PACKET		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	07/03/2003	

**Labeler** - China Resources Sanjiu Medical & Pharmaceutical Co Ltd (544695711)

**Registrant** - China Resources Sanjiu Medical & Pharmaceutical Co Ltd (544695711)

### Establishment

Name	Address	ID/FEI	Business Operations
China Resources Sanjiu Medical & Pharmaceutical Co Ltd		544695711	manufacture(12753-307)

Revised: 9/2013

China Resources Sanjiu Medical & Pharmaceutical Co Ltd